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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/424,347	07/18/2000	HITOSHI ENDOU	49429	7848

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EXAMINER

MURPHY, JOSEPH F

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 06/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/424,347	ENDOU ET AL.
	Examiner	Art Unit
	Joseph F Murphy	1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 27 March 2003.

2a) This action is FINAL.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 17-20 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 17-20 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.

4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_.

## DETAILED ACTION

### *Formal Matters*

Claims 1-16 were canceled, claim 17 was amended and new claims 18-20 were added in Paper No. 18, 3/27/2003. Claims 17-20 are pending and under consideration.

### *Response to Amendment*

The objection to claim 17 has been obviated by Applicant's amendment and is thus withdrawn.

The rejection of claim 17 under 35 USC § 112 second paragraph has been obviated by Applicant's amendment and is thus withdrawn.

The rejection of claim 17 under 35 U.S.C. 102(a) as being anticipated by Sweet et al. (1997) has been obviated by the English translation of the Japanese priority document, and is thus withdrawn.

The rejection of claim 17 under 35 U.S.C. 102(a) as being anticipated by Sekine et al. (1997) has been obviated by the English translation of the Japanese priority document, and is thus withdrawn.

### *Claim Objections*

Claim 17 is objected to because of the following informalities: The term "amino acid" is misspelled. Appropriate correction is required.

***Claim Rejections - 35 USC § 112 second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17 is indefinite because it is drawn to a protein comprising the amino acid sequence shown in SEQ ID NO: 2, wherein at least one amino acid residue has been deleted, substituted or added. The claim encompasses an infinite number of proteins, because any number of amino acids can be deleted, substituted, or added. The claim does not have any reasonable limitations, thus the metes and bounds of the claim cannot be determined.

Claims 18-20 are indefinite in the recitation of the term "derived from". It is unclear whether this term imposes a required limitation on the claim, such that it only encompasses, for example, the method when practiced with polypeptides isolated from rats or human or kidney tissue sources, or if the claims also encompass methods wherein the polypeptide is produced recombinantly or synthetically. Thus, the metes and bounds of the claims cannot be determined.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Kanai et al. (1996).

Kanai et al. teach that the cDNA for the rat liver organic anion-transporting polypeptide "oatp" has been shown to encode transport of bromosulfophthalein (BSP) and bile salts in *Xenopus* oocytes. Kanai et al. sought to determine whether renal oatp might play a role in the known secretion of a large variety of organic anions by the kidney. Kanai et al. teach a method wherein a full-length oatp cDNA is transiently expressed, cloned in pSPORT, in HeLa cell monolayers using the recombinant vaccinia virus vtf7-3 (page F319, column 2, fourth paragraph). Kanai et al. tested an array of organic anions as candidate substrates by determining their ability to compete with tracer BSP for transport (page F322, Figure 5 and 6). The method of Kanai et al. anticipates the claimed invention because claim 17 is drawn to a method of screening for compounds with an effect on the organic anion transport function of a protein which has at least one amino acid deletion, substitution or addition. Because of the indefinite nature of claim 17, where the structural limitation has neither an upper nor lower limit on the number of additions, substitutions or deletions possible, the protein used by Kanai et al. in their method anticipates claim 17. Due to the indefinite nature of the term "derived from" claims 18-20 are also anticipated, since it is not clear what limitation the term "derived from" imposes on the claim.

***Conclusion***

No claim is allowed.

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F. Murphy whose telephone number is 703-305-7245. The examiner can normally be reached on M-F 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 703-308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Joseph F. Murphy, Ph. D.  
Patent Examiner  
Art Unit 1646  
June 18, 2003

*Gary d. Kunz*  
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